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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,412	04/15/2004	Sabine Behrends	Serie 6292	9359

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EXAMINER

MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

MAIL DATE	DELIVERY MODE
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08/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,412

Applicant(s)

BEHRENDT ET AL.

Examiner

Leigh McKane

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-25 and 28-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-25 and 28-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 48 is confusing in view of claim 23 from which it depends. Claim 23 requires a weight ratio of glycerol to alcohol of 0.09 or less. Therefore, an amount of glycerol of 20%, as set forth in claim 48, would require an amount of alcohol of 250%.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 23-25, 28-33, 35-40, 42, 43, 45-63, 65, 69, 70, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al. (US 5,539,001) in view of Tu et al. (WO 92/09309).

With respect to claims 23-25, 28-33, 35-37, 59, 63, 65, 69, 70, and 72, Waldmann-Laue et al. teaches a method for the disinfection of hard surfaces using a composition containing an aromatic alcohol and a glycerol ether having a C₆₋₂₂ alkoxymethyl group. See Abstract and Formula II (col.1, lines 50-57). The ether to alcohol weight ratio is 1:9, which converts to 0.11.

Art Unit: 1744

See Abstract. As 0.11 is so close to applicant's claimed ratio of 0.09, the Examiner submits that the claimed ratio would have been obvious over that disclosed by Waldmann-Laue et al. in the absence of unexpected results. The composition disclosed by Waldmann-Laue et al. may be an aqueous or anhydrous solution. See col.2, lines 6-10. The aromatic alcohol may be benzyl alcohol (an arylalkanol) or phenylethanol (an arylalkanol). See col.2, lines 11-14. The composition may further include a salt, magnesium sulfate (col.3, line 30) and is effective against bacteria and fungi (col.3, lines 44-48 and Examples). Waldmann-Laue et al. discloses treatment at ambient temperatures. Tu et al., however, teaches a method of sterilization of hard surfaces using a mixture of a glycidyl ether and an aromatic alcohol. Tu et al. further discloses that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to increase and optimize the treatment temperature, an established result effective variable, based upon the particular concentration of sterilant used and the amount of contamination present, to both increase the percent kill and to reduce the treatment time.

As to claims 39 and 40, Waldmann-Laue et al. fails to teach a method of application on hard surfaces. Tu et al., however discloses that the hard surface may be submerged in the disinfectant for sterilization (page 7, lines 22-24). As submerging (dipping) the hard surface promotes contact and wetting of the entire surface with the disinfectant, it would have been obvious in the method of Waldmann-Laue et al..

With respect to claim 42, Waldmann-Laue et al. teaches the disinfection of "hard

Art Unit: 1744

surfaces” but does not enumerate any specific surfaces. However, one of ordinary skill in the art at the time of the invention would have recognized the term “hard surfaces” to include at least one of metal, glass, plastic, and ceramic, as known in the art.

With respect to claim 43, Waldmann-Laue et al. is silent with respect to disinfecting a medical instrument. However, Tu et al. teaches that medical instruments can be successfully sterilized using organic ether compositions. Thus, it would have been obvious to one of ordinary skill in the art to use the composition of Waldmann-Laue et al. to sterilize medical instruments in the manner of Tu et al.

As to claims 45-47, Waldmann-Laue et al. fails to teach a treatment time. Tu et al. discloses that “[t]he optimum sterilization time is related to the quantity of microorganism present and the level of sterility assurance desired. Consequently, the time can be varied according to needs.” See page 8, lines 1-4. In view of the teachings of Tu et al., it would have been obvious to optimize treatment time according to other result effective variables, such as concentration of disinfectant, treatment temperature and the quantity of microorganisms present.

With respect to claims 48-58, Waldmann-Laue et al. discloses that the antimicrobial diol (glycerol ether) and the alcohol are present in a ratio of 9:1 to 1:9 (claim 1). This means that the glycerol ether is present in an amount of 10-90% of the composition before any dilution and the alcohol is present in an amount from 90-10% before any dilution. It is deemed obvious to one of ordinary skill in the art to optimize the relative amounts of the glycerol ether and the alcohol for the particular use of the composition. Moreover, one would have found it obvious to also optimize the dilution amount for the same reasons. The optimization of concentration, a result

Art Unit: 1744

effective variable, is readily determined through routine experimentation and is deemed obvious in the absence of unexpected results.

With respect to claim 60, while Waldmann-Laue et al. is silent with respect to the treatment pH, it would have been obvious to maintain the pH near neutral in order to avoid the corrosive effects of a strong basic or acidic solution.

As to claims 61-62, Waldmann-Laue et al. teaches generally C₆₋₂₂ alkyls which include both straight and branched chains. Moreover, a chain length of 6 to 22 carbon atoms in the alkoxymethyl group encompasses the claimed ethers and thus, they are rendered obvious by the disclosure of Waldmann-Laue et al..

5. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al. in view of Tu et al. as applied to claim 23 above, and further in view of Langford (US 5,906,802).

The combination of Waldmann-Laue et al. with Tu et al. discloses the use of elevated temperatures but does not teach using an elevated pressure. Langford discloses that using alternating cycles of pressure and suction, assists with the cleaning action and assures that any sterilant is forced throughout the medical instrument. See col.8, lines 55-59. Since the combination of Waldmann-Laue et al. with Tu et al. teaches the sterilization of medical instruments, it would have been obvious to apply the method of cyclic pressurization of Langford to method of the combination.

6. Claims 41 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al. and Tu et al. as applied to claims 23 and 69 above, and further in view of Saud et al. (US 2004/0001797).

Art Unit: 1744

With respect to claim 41, Waldmann-Laue et al. does not teach atomizing the composition. Saud et al. discloses a disinfecting composition containing a glycerol ether in combination with an alcohol. The composition may be dispensed from a spray bottle (i.e. atomized). See paragraph [0054]. As atomization is an efficient means of providing even coverage of a surface, it would have been an obvious means of dispensing the composition of Waldmann-Laue et al..

As to claim 71, Waldmann-Laue et al. is silent with respect to triclosan within the composition. Saud et al. teaches a disinfecting composition containing a glycerol ether in combination with an alcohol. The composition may additionally include Triclosan to further improve the disinfecting action (paragraph [0037]). For this reason, it would have been obvious to include Triclosan in the composition of Waldmann-Laue et al..

7. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al. and Tu et al. as applied to claim 43 above, and further in view of Miner et al. (US 6,096,348).

The combination of Waldmann-Laue et al. with Tu et al. teaches the treatment of hard surfaces but not the treatment of an endoscope. Miner et al. discloses it was known in the art at the time of the invention that medical instruments such as endoscopes are particularly hard to sterilize due to their sensitivity to high temperatures and pressures. As the sterilant of Waldmann-Laue et al. is effective at low temperatures, it would have been obvious to use for the sterilization of endoscopes.

Art Unit: 1744

8. Claims 64 and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al. and Tu et al. as applied to claims 23 and 63 above, and further in view of Eggensperger et al. (US 5,393,789).

Although Waldmann-Laue et al. teaches the use of an aromatic alcohol as an essential part of the composition, an aryloxyalkanol is not disclosed. Eggensperger et al. teaches a surface disinfectant including an antimicrobial in combination with an aromatic alcohol. Suitable aromatic alcohols include the arylalkanols (phenyl ethanol, phenyl propanol, benzyl alcohol) of Waldmann-Laue et al. as well as, aryloxyalkanols (phenoxyethanol, phenoxypropanol) and oligoalkanol aryl ethers. See col.2, lines 41-68. As the disclosure of Eggensperger et al. teaches the functional equivalence of these three types of aromatic alcohols, one of ordinary skill in the art would have found it obvious to substitute one for another in the composition of Waldmann-Laue et al. and to have an expectation of success when doing so.

Furthermore, when making the substitution suggested by Eggensperger et al. one would have kept the same proportions taught by Waldmann-Laue et al. and diluted the concentrate according to the desired use.

9. Claims 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (US 5,906,802) in view of Waldmann-Laue et al..

Langford teaches a method of sterilizing a medical instrument wherein the instrument is first cleaned with a detergent to remove bioburden therefrom, disinfected with a liquid or gas sterilant, rinsed with sterile water, and then dried. See col.1, lines 40-52; col.2, lines 35-42; col.3, lines 16-19; col.5, lines 25-26. Although Lanford is silent with respect to a disinfection time, it is deemed obvious to optimize the time the sterilant is in contact with the instrument

Art Unit: 1744

dependent upon the concentration of sterilant, the temperature of the sterilant, and the amount of contamination present. Langford does not disclose use of an alkyl glycerol ether as the sterilant. Waldmann-Laue et al. teaches a method for the disinfection of hard surfaces using a composition containing an aromatic alcohol and a glycerol ether having a C₆₋₂₂ alkoxymethyl group. Since the sterilant of Waldmann-Laue et al. is effective at low-temperatures, it would have been an obvious choice for the sterilization of the thermolabile medical instruments of Langford. With respect to “pre-cleaning” (i.e. rinsing) the instrument with water before the initial step of cleaning, Langford discloses that the method employs several cycles of washing, either with or without a detergent, in order to completely remove the bioburden prior to sterilization. See col.1, lines 47-51.

10. Claims 73-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford in view of Waldmann-Laue et al. and Tu et al..

As to claim 73, Langford teaches a method of sterilizing a medical instrument wherein the instrument is first cleaned with a detergent to remove bioburden therefrom, disinfected with a liquid or gas sterilant, rinsed with sterile water, and then dried. See col.1, lines 40-52; col.2, lines 35-42; col.3, lines 16-19; col.5, lines 25-26. Langford fails to teach a treatment time. Tu et al., however, discloses that “[t]he optimum sterilization time is related to the quantity of microorganism present and the level of sterility assurance desired. Consequently, the time can be varied according to needs.” See page 8, lines 1-4. In view of the teachings of Tu et al., it would have been obvious to optimize treatment time according to treatment temperature and the quantity of microorganisms present. Langford does not disclose use of an alkyl glycerol ether as the sterilant. Waldmann-Laue et al. teaches a method for the disinfection of hard surfaces using

Art Unit: 1744

a composition containing an aromatic alcohol and a glycerol ether having a C₆₋₂₂ alkoxymethyl group. Since the sterilant of Waldmann-Laue et al. is effective at low-temperatures, it would have been an obvious choice for the sterilization of the thermolabile medical instruments of Langford.

With respect to claim 74 and “pre-cleaning” (i.e. rinsing) the instrument with water before the initial step of cleaning, Langford discloses that the method employs several cycles of washing, either with or without a detergent, in order to completely remove the bioburden prior to sterilization. See col.1, lines 47-51.

As to claims 75-80, Langford fails to disclose a treatment temperature. Tu et al. teaches in a method of sterilization that the “percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time.” For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to optimize the treatment temperature according to the type of instrument being sterilized to both increase the percent kill and to reduce the treatment time.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Art Unit: 1744

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-33, 37, and 51-53 of copending Application No. 10/445,715 in view of Tu et al.. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending claims substantially encompasses the subject matter of the instant claims. The co-pending claims do not claim a treatment temperature. Tu et al., however, teaches in a method of sterilization that the “percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time.” For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to optimize the treatment temperature according to the type of instrument being sterilized to both increase the percent kill and to reduce the treatment time.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 73-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 67-73, 75, and 80 of copending Application No. 10/825,266. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the copending application and the instant claims differ

Art Unit: 1744

only in that the instant claims recite “thermal” disinfection. However, as no particular temperature is claimed, the copending claims read on the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

14. Applicant's arguments filed 8 June 2007 have been fully considered but they are not persuasive.

15. While Applicant argues that Waldmann-Laue et al. fails to teach the claimed ratio of ether to alcohol of 0.09, Waldmann-Laue et al. does disclose a ratio of 0.11. Given the proximity of the two ratios, the ratio Waldmann-Laue et al. renders obvious that which is claimed in the absence of unexpected results.

16. Applicant contends that neither Langford nor Waldmann-Laue et al. disclose a treatment time of 1 to 20 minutes as claimed in amended claim 73. However, in the absence of unexpected results, it is submitted that the optimization of treatment time, a known result effective variable, is within the purview of one of ordinary skill in the art.

17. With respect to Tu et al., applicant asserts that Tu fails to disclose that thermal disinfection is even possible from about 1 to about 20 minutes of disinfection. However, Tu et al. employs a different sterilant composition. Regardless, Tu et al. was relied upon because this reference recognizes that treatment time is a result effective variable.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

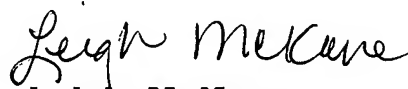
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1744

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leigh McKane
Primary Examiner
Art Unit 1744

elm
14 August 2007